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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,883

12/15/2003

Diane Lipscombe

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

12/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/736,883	Applicant(s) LIPSCOMBE ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,37 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,37 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Claims 1, 37 and 41 are pending in the instant application. Claim 1 has been amended and claims 2 to 4, 38 to 40 and 42 to 44 have been canceled as requested by Applicant in the correspondence filed 21 October of 2008.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

4) Figures 10 to 17 of the instant application do not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a **capital** letter. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly. M.P.E.P. 601.01(g) states that "if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected".

Claim Rejections - 35 USC § 112

5) Claims 1, 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims encompass a an isolated cell that “recombinantly expresses SEQ ID NO:45 or fragments thereof that retain N-type calcium channel voltage regulated calcium influx activity”. It is noted that SEQ ID NO:45 of the instant application is an amino acid sequence. Applicant is advised that an amino acid sequence is a **property** of a compound and not a material entity in and of itself. Therefore, the instant specification fails to disclose a cell that expresses a sequence or a sequence that has activity. It is recommended that Applicant consider replacing the phrase “SEQ ID NO:45 with such language as “a polypeptide comprising SEQ ID NO:45”, “a polypeptide having the amino acid sequence of SEQ ID NO:45”, or “a Cav2.2e calcium channel subunit comprising SEQ ID NO:45”.

In addition, these claims are not enabled because there is absolutely no description provide in the instant specification of a polypeptide comprising SEQ ID NO:45, or a fragment thereof, and possessing any type of calcium influx activity. As illustrated in Figure 10 of the instant application and described on page 1 therein, an active calcium channel of the instant invention is a homomeric membrane spanning protein complex whose subunits have very complicated structures consisting of a plurality of extracellular, transmembrane and cytoplasmic domains. The amino acid sequences of orthologous subunits from a number of different mammals are provided in SEQ ID NOs:28, 30, 32, 34, 38, 40, 42 and 44 of the instant application. It is noted that not one of these sequences is less that 2200 amino acids in length. Because the

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instant specification does not provide even a single working example of a functional $\text{Ca}_v2.2$ calcium channel subunit having anything less than a native amino acid sequence or the guidance needed to predictably alter the native sequence of a $\text{Ca}_v2.2$ calcium channel subunit, one of ordinary skill has no reasonable expectation of producing a functional calcium channel having no more than the 33 amino acid long sequence presented in SEQ ID NO:45 of the instant application.

Further, because the amino acid sequence of SEQ ID NO:45 is identical in the corresponding proteins from humans, rats and mice, as disclosed in lines 29 to 31 on page 3 of the instant specification, an artisan has no reasonable expectation that a $\text{Ca}_v2.2$ calcium channel subunit comprising that sequence will tolerate any modifications thereto.

In summary, whereas the instant specification is enabled for the production of “a cell comprising a recombinant nucleic acid encoding SEQ ID NO:45”, “an isolated cell that recombinantly expresses a polypeptide comprising SEQ ID NO:45”, “a cell comprising a recombinant nucleic acid encoding a mammalian $\text{Ca}_v2.2$ calcium channel subunit comprising SEQ ID NO:45”, and “an isolated cell that recombinantly expresses a mammalian $\text{Ca}_v2.2$ calcium channel subunit comprising SEQ ID NO:45”, it is not enabled for a cell that produces a polypeptide having N-type calcium channel voltage regulated calcium influx activity wherein that polypeptide comprises nothing more than the amino acid sequence of SEQ ID NO:45 or a fragment thereof. A claim is not enabled when it requires a function and fails to recite the structural elements that are needed to provide that function. Applicant is advised that the allowability of the enabled

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subject discussed above has yet to be determined since that subject matter is not encompassed by the instant claims. The fact that subject matter is found to be enabled does not necessarily mean that it is free of the prior art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 1, 37 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is vague and indefinite because it is unclear if the limitation “expresses SERQ ID NO”45” is open or closed. Claims 37 and 41 are vague and indefinite in so far as they depend from claim 37 for this element.

Response to Arguments

7) Applicant's arguments with respect to claims 1, 37 and 41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649

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